

DEC 8 2005

510(k) SUMMARY as required by 807.92
Summary of Safety & Effectiveness Information

1. Device Name

Proprietary Name

SURFLO® Winged Infusion Set with Needle Protection (Surshield™)

Classification Name

Intravascular Administration Set (80FPA)

21CFR, Section 880.5440

Classification: Class II

2. Reason for Submission

New Device

3. Intended Use

The Surflo Winged Infusion Set with Needle Protection (Surshield) is intended to access the peripheral vascular system, for intravenous administration of fluids and/or withdrawal of blood specimens using a syringe, luer adapter, or other compatible/appropriate devices. Additionally, after withdrawal of the needle from the patient's vein, the shield cover can be manually activated to cover the needle to minimize risk of accidental needle stick.

4. Description

The Terumo Surflo Winged Infusion Set with Needle Protection (Surshield) is a sterile, single use device consisting of a needle attached to a winged hub, tubing, adapter and adapter cap, and a hinged shield cover that attaches to the wing just below the needle-to-wing junction.

The shield cover can be turned 180 degrees on the hinge. As the needle is removed from the patient's vessel, the user's finger actively pushes the shield cover until it latches onto needle using a one- or two- handed technique. An audible click is noted upon activation. The shield cover is designed to allow the user's finger to remain behind the needle point so that the risk of needle stick injury is minimized. The shield cover is transparent for easy confirmation of the needle held in it.

The device possesses 350 mm length tubing.

5. Substantial Equivalence

The “Surflo Winged Infusion Set with Needle Protection (Surshield)”, manufactured by Terumo Europe N.V., submitted in this 510(k) file is substantially equivalent in intended use, description/specifications, technology/principles of operation, materials and performance to the cleared “Surshield Safety Winged Infusion Set”, manufactured by Terumo Medical Products in Hangzhou, China, which is the subject of K031266.

6. Additional Safety Information

The sterility of the Surflo Winged Infusion Set with Needle Protection (Surshield) is assured by using a validated sterilization method qualified in accordance with EN 550: "Sterilization of Medical Devices: Validation and routine control of ethylene oxide" and ISO 11135: "Medical Devices: Validation and routine control of ethylene oxide sterilization" to a sterility assurance level (SAL) of 10^{-6} as required by EN 556-1: "Sterilization of Medical Devices - Requirements for medical devices to be designated "STERILE" - Part - 1: Requirements for terminally sterilized medical devices".

Ethylene oxide residual levels resulting from EtO sterilization are in compliance with ISO 10993-7: "Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals" and do not exceed the level proposed in the European Pharmacopeia monograph 3.2.6:

Ethylene Oxide ≤ 10 ppm

Ethylene Chlorohydrin ≤ 10 ppm

The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard EN ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and testing. Results of the testing demonstrate that the blood contacting materials are biocompatible.

The expiration dating for the Surflo Winged Infusion Set with Needle Protection (Surshield) has been established at 5 years.

7. Conclusion

The Surflo Winged Infusion Set with Needle Protection (Surshield) manufactured by Terumo Europe N.V. and submitted in this 510(k) file is substantially equivalent in intended use, description, specifications, technology/principles of operation, materials and performance to the cleared Surshield Safety Winged Infusion Set manufactured by Terumo Medical Products in Hangzhou, China, which is the subject of K031266. Differences between the devices do not raise any new issues of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 8 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mrs. M.J. Aerts
Manager Regulatory Affairs
Terurmo Europe N.V.
Researchpark Zone 2,
Interleuvenlaan 40, 3001 Leuven
BELGIUM

Re: K052887
Trade/Device Name: Surflo® Winged Infusion Set with Needle Protection
(Surshield™)
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 7, 2005
Received: October 13, 2005

Dear Mrs. Aerts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known): K052887

Device Name: Surflo® Winged Infusion Set with Needle Protection (Surshield™)

Indications for Use:

The Surflo Winged Infusion Set with Needle Protection (Surshield) is intended to access the peripheral vascular system, for intravenous administration of fluids and/or withdrawal of blood specimens using a syringe, luer adapter, or other compatible/appropriate devices. Additionally, after withdrawal of the needle from the patient's vein, the shield cover can be manually activated to cover the needle to minimize risk of accidental needle stick.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

William M. Burdick 12/18/05

Special Anesthesiology, General Hospital,
Anesthesia Control, Dental Devices

Number K052887

Page 1 of 1